83-69

No. ..-...

IN THE

Supreme Court of the United States

October Term, 1983

THE UPJOHN COMPANY,*

Petitioner,

vs.

O. L. MAULDIN,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

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Question Presented.

Did allowing a lay jury to find that two prescription drugs manufactured by defendant medically caused plaintiff's disease in the total absence of expert testimony to that effect, violate the defendant's constitutional right to a trial by a jury capable and willing to decide the case solely on the evidence before it?

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Note, The Right to a Jury Trial in Complex Civil Litigation, 92 Harv. L. Rev. 898 (1979) 8

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Medical Authorities

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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

Introduction.

The petitioner the Upjohn Company ("Upjohn") respectfully prays that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit originally rendered on February 7, 1983, and denied again on petition for rehearing and suggestion for rehearing en banc on April 18, 1983.

Opinion Below.

The opinion of the United States Court of Appeals for the Fifth Circuit is officially reported in 697 F.2d 644 (February 7, 1983) and is printed in Appendix A, pp. 1-9 hereto, *infra*.

Jurisdiction.

The judgment of the United States Court of Appeals for the Fifth Circuit was originally entered on February 7, 1983. A Petition for Rehearing and Suggestion for Rehearing En Bank were duly filed by Upjohn on March 23, 1983 and denied on April 18, 1983. This petition for Certiorari if being filed within 90 days of that last date. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

Constitutional Provision Involved.

The Fifth Amendment to the United States Constitution guarantees that, "No person shall be . . . deprived of life, liberty, or property, without due process of law. . . ."

Statement of the Case.

In March of 1974, Respondent O. L. Mauldin crushed and virtually amputated part of his thumb. In order to minimize the risk of life-threatening infection, Mauldin's treating physician prescribed Lincocin and Cleocin, two strong, broad-spectrum antibiotics manufactured by Petitioner Upjohn which are noted for their effectiveness in combating such infections.

Shortly after using Upjohn's drugs, Mauldin began to suffer acute diarrhea, elevated temperatures, and a series of other symptoms diagnosed by his treating doctors as either gastroenteritis or acute ulcerative colitis. As a result of his disease, whatever it was, Mauldin underwent major surgery.

Mauldin subsequently sued Upjohn, alleging that his brief use of Lincocin and Cleocin caused the disease which necessitated his surgery and that Upjohn was liable to him for failing adequately to warn prescribing doctors of the risk that the drugs could cause such a disease.

Two principal issues were tried: First, whether Cleocin and Lincocin medically caused Mauldin's disease; and, Sec-

ond, whether Upjohn knew, or should have known, that the drugs might cause such a disease and failed adequately to warn prescribing physicians of that risk.

A number of medical experts testified at trial that the symptoms suffered by Mr. Mauldin were consistent with both acute idiopathic ulcerative colitis (that is, a type of colitis of unknown origin) and a related but different disease known as pseudomembranous colitis.[1]

Experts further testified that virtually all antibiotics may cause pseudomembranous colitis on occasion (R.T. Vol. V, p. 44); that the medical profession has known about the disease since the latter part of the last century [well before antibiotics were discovered and used] (R.T. Vol. II, p. 64, lines 19-21); that at least one other drug used by Mr. Mauldin shortly before his operation is known to cause pseudomembranous colitis (R.T. Vol. II, p. 127, lines 10-11); and that pseudomembranous colitis occurs in persons who have not used antibiotics.

Respecting causes other than drug use, Mauldin's principal expert testified that pseudomembranous colitis occurs "[q]uite often in a seriously ill person after an operation, an accident, or a depleting illness" (R.T. Vol. II, p. 73); that pseudomembranes may occur with other types of colitis

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[1]Expert testimony also established that the term "pseudomembranous colitis" refers to a false membrane which appears to cover the intestine in a number of different gastrointestinal diseases. In its chapter entitled "The Pseudomembranous Enterocolitides", a leading medical text, *Gastrointestinal Disease, 2d ed.*, edited by Sleisenger and Fordtran, describes the condition as follows:

> "The formation of the Pseudomembranes on the surface of the small or large intestine is a nonspecific response to injury and only one of the limited pathologic patterns seen in intestinal disease. Thus is is not surprising that *when all cases demonstrating pseudomembranes are considered together, multiple causes are included.*"
>
> *Gastrointestinal Disease, supra*, at 1715 (footnotes omitted, emphasis added.)

(*id.*); and that pseudomembranes may appear in conjunction with idiopathic ulcerative colitis (colitis of unknown cause), one of the diseases Mauldin's treating physicians suspected him of having. (R.T. Vol. II, p. 75).

Because extensive scientific research has revealed that antibiotics *may* cause such illnesses, one leading researcher testified that Lincocin-and Cleocin-associated pseudomembranous colitis should be considered in a "differential diagnosis" involving any patient who has signs and symptoms similar to those suffered by Mr. Mauldin following use of antibiotics such as Lincocin and Cleocin. (R.T. Vol. V, p. 44, lines 15-25).

In summary, the experts testified that a disease like Mr. Mauldin's may result from a number of causes, known and unknown, including the use of antibiotics such as Lincocin and Cleocin, as well as from operations, accidents, and depleting illnesses.

The experts also testified regarding the substantial difficulty experienced by highly-trained specialists in discovering whether Lincocin and Cleocin can cause the type of pseudomembranous colitis allegedly suffered by Mr. Mauldin in some unknown, but small, percentage of users. (R.T. Vol. V, p. 43).

Surprisingly, despite the number and broad experience of the experts used at trial, not one of them testified that the use of Lincocin and Cleocin probably, possibly, may have, could have, or even conceivably might have caused Mr. Mauldin's disease. There was, in short, not one whit of expert testimony regarding the medical cause of Mauldin's disease.

The record does not reveal why the experts did not identify either at trial or in Mr. Mauldin's medical records, what caused his unfortunate illness. Perhaps they forgot. Perhaps

they were unable or unwilling to determine what caused his disease. Whatever the reason, the record contains no such evidence, as the opinion of the Fifth Circuit clearly concedes. *Mauldin v. Upjohn Co.*, 697 F.2d 644, 646 (5th Cir. 1983).

Upjohn repeatedly raised this evidentiary deficiency at trial, moving initially for a directed verdict (R.T. Vol. V, p. 11) and subsequently for judgment notwithstanding the jury's verdict and a new trial — all of which were denied. *Mauldin v. Upjohn Co., supra* at 646.

The same point was argued with vigor to the Fifth Circuit, which concluded (among a number of other substantive and procedural issues) that the absence of expert testimony connecting Lincocin and Cleocin with Mauldin's illness was not fatal to his case because "the record contains circumstantial evidence that either Lincocin or Cleocin caused Mauldin's disorder sufficient to require submission of that question to the jury." *Mauldin v. Upjohn Co.*, 697 F.2d 644, 646 (5th Cir. 1983).

Cryptically, the Circuit's opinion does not identify the "circumstantial evidence" which it found "sufficient" to take the matter to the jury or explain why a lay jury would be competent to infer medical causation from such evidence when Mauldin's treating doctors and expert witnesses failed to do so.

In essence, the Fifth Circuit held that a lay jury, not learned in medical science or in the complex and arcane disciplines relied upon by medical science to distinguish medical causation from rank coincidence and wholly unguided by the testimony of anyone expert in those disciplines, could competently conclude that the drugs involved

more probably than not caused Mauldin's disease.[2]

We submit this holding denied Upjohn its constitutional right to trial by a jury competent to decide the issues; runs directly contrary to established precedent in the Fifth and other Circuits; totally misconstrues this Court's holding in *Sentilles v. Inter-Caribbean Corporation*, 361 U.S. 107 (1959); and turns the law — long-established nationwide — relating to the proper roles of experts and juries in deciding such highly technical issues on its ear.[3]

Furthermore, wholly aside from the impact of the fifth circuit's ruling in this case, Petitioner Upjohn earnestly submits that allowing juries to decide highly complex, technical

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[2]All prescription drugs cause adverse side effects. Determining whether a drug actually causes a given medical effect (good or bad) is a highly complex matter since virtually all human ailments or "effects" have a "natural incidence" in that they will occur in the total absence of drug use, or other identifiable cause. When ailments develop at or about the same time a drug is being used for reasons unrelated to the drug, the temporal relationship between use of the drug and onset of the ailment is pure *coincidence*.

Similarly, a drug may be used to reduce the risk of a given ailment, such as blood-pressure reducing medication used to reduce the risk of heart attack because no drug is 100% effective, some people taking such medication will suffer heart attacks at or about the same time they are taking it. The temporal relationship here reflects incidence of the disease *in spite of*, not because of, the use of the medication.

Because it is extremely difficult to determine whether the appearance of a disease at or about the time a particular drug is being used is coincidental or actually shows a causal relationship, medical science relies on specialists known as "epidemiologists" to determine whether such caused relationships exist. Making such determinations requires highly specialized training, detailed data, and the application of analytical techniques all of which fall far outside the scope of common knowledge and understanding. Consequently, such judgments *must* be made by experts.

[3]This Petition asserts a federal constitutional right. Furthermore, in a diversity case in the Fifth Circuit, a federal standard is applied in determining whether trial evidence is sufficient to create a jury question and to defeat a motion for directed verdict or judgment n.o.n. *Boeing Co. v. Shipman*, 411 F.2d 365 (5th Cir. 1969). Federal law regarding the indispensability of expert testimony in such circumstances thus controls.

issues falling well outside the common knowledge and experience of laymen — totally unguided by testimony from persons specially qualified by knowledge, skill, experience, training, or education in the discipline involved — would invite an exponential increase in litigation involving facially attractive but technically specious propositions; would deny plaintiffs and defendants, alike, their constitutional right to a trial by jurors who *are competent* to decide the issues presented to them; and would thrust juries squarely into the province of deciding complex questions in a context offering no realistic hope that they truly understand the facts and issues involved — a role that Anglo-American jurisprudence never contemplated for lay juries and for which they are simply not equipped.

ARGUMENT FOR GRANTING THE WRIT.

A. THIS PETITION PRESENTS A QUESTION OF BROAD APPLICATION AND CONSTITUTIONAL DIMENSIONS.

The issue raised by this Petition far transcends the dispute between the parties. It goes to the very core of the constitutional right of all litigants to trial by ". . . a jury *capable* and willing *to decide the case* solely on the evidence before it. . . ." *Smith v. Phillips*, 455 U.S. 209, 217 (1982) (emphasis added).

How and if juries should be used to deal with highly complex and demanding technical issues are issues being raised with increasing frequency in an expanding range of contexts.[4] The existence of this active debate reflects the

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[4]*Cases:*
Gwathmey v. United States, 215 F.2d 148 (5th Cir. 1954); *Citron v. Aro Corp.*, 377 F.2d 750 (3rd Cir. 1967); *United States v. Central Supply Ass'n.*, 6 F.R.D. 526 (N.D. Ohio 1947); *Hyde Properties v. McCoy*, 507 F.2d 301 (6th Cir. 1974); *Prudential Oil Corp. v. Phillips Petroleum*, 392 F.Supp. 1018 (S.D.N.Y. 1975, rev'd. on other grounds, 546 F.2d 469 (2d Cir. 1976); *American Can Co. v. Dart Industries*, 205 U.S.P.Q. 1007 (1979); *Bernstein v. Universal Pictures*, 79 F.R.D. 59 (S.D.N.Y. 1978); *In re Boise Cascade Securities Litigation*, 420 F.Supp. 99 (W.D. Wash. 1976); *In re United States Financial Securities Litigation*, 609 F.2d 411 (9th Cir. 1979); *Radial Lip Mach. Inc. v. Intern. Carbide Corp.*, 76 F.R.D. 224 (N.D. Ill. 1977); *United States v. J. B. Williams Co. Inc.*, 498 F.2d 414 (2nd Cir. 1974); *Davis v. Firestone Tire and Rubber Company*, 196 F.Supp. 407 (N.D. Cal. 1961); *United States v. Staggs*, 553 F.2d 1073 (7th Cir. 1977); *Complaint of American Export Lines Inc.*, 73 F.R.D. 454 (S.D.N.Y. 1977); *Frisone v. United States*, 270 F.2d 401 (9th Cir. 1959); *In Re Swine Flu Immunization, Products Liability Litigation*, 533 F.Supp. 703 (D.C. Ut. 1982).

Commentaries:
Note, *Preserving The Right To Jury Trial In Complex Civil Cases*, 21 Stan. L. Rev. 99 (1979); Note, *The Right To A Jury Trial In Complex Civil Litigation*, 92 Harv. L. Rev. 898 (1979); Note, *Jury Trials In Protracted Commercial Litigation*, 10 Conn. L. Rev. 775 (1978); Note, *Unfit For Jury Determination: Complex Civil Litigation And The Seventh Amendment Right of Trial By Jury*, 20 B.C.L.Rev. 511 (1979); Schaeffer, *Is The Adversary System Working In Optimal Fashion?* 70 F.R.D. 79 (1976); Kirkham, *Complex Civil Litigation — Have Good Intentions Gone Awry?* 70 F.R.D. 79 (1976); O'Connell, *Jury Trials in Civil Cases*, 58 Ill. B. J. 796, 800 (1970).

impact of society's increasing technical specialization on our judicial processes; the ever-widening gulf between instinct and intellect which the technological revolution has wrought; and an increasing awareness of "the practical abilities and limitations of juries." *Ross v. Bernhard*, 396 U.S. 531, 538 n.10 (1970).

Life presents each of us, daily, with a bewildering array of decisions. With some of these we are well equipped to deal using "common sense," personal experience, and acquired skills. The more complex of these decisions, however, are beyond our intellectual and experiencial scope, necessitating our reliance on specially trained individuals to translate those complexities which transcend our understanding into terms with which we are competent to deal and to advise us based upon their specialized capabilities.

As microcosms of our society, juries are faced with a similar dichotomy. Some judgments they are called upon to make fall squarely within the scope of common knowledge and judgmental competence: Did someone exercise reasonable care in the driving of his automobile or the fencing-in of his animals? Was he drunk? How old was he? Is the witness believable?

Many issues which juries increasingly are called upon to decide, however, fall totally outside the realm of common knowledge and experience: Did pilot error cause an air crash? Was a skyscraper adequately designed to withstand earthquakes? Did a physician meet the applicable standard of medical care in making his diagnosis, or identifying the cause and administering the treatment respecting a patient's illness?

Lay juries are not equipped to deal with such issues on their own for the simple reason that common sense and knowledge frequently lead us astray when applied to such

complex technical questions. Indeed, the pitfalls inherent in applying "common sense" to complex technical issues are many and varied. In the absence of scientific data and analysis, for example, common sense applied to sensory perceptions led mankind to believe for centuries that the earth was both flat and at the center of the universe. In the absence of scientific proof to the contrary, provided by physicists, mathematicians, and astronomers, even the most intelligent person likely would believe both of those propositions to be true even today.

In order to protect juries against being led astray by superficially appealing but specious propositions, the law has traditionally required parties burdened with proving facts falling outside the sphere of common knowledge and understanding to prove those facts through the use of expert testimony. Only through the medium of expert testimony may evidence bearing on such issues be translated into a form which will allow persons not learned in the discipline involved to be "capable" of reaching reasoned judgments respecting such issues.

Being "capable" of deciding a case based on the evidence, as required by the due process clause, means that a jury not only must possess the ability to *perceive* the evidence, but must also be able to *understand* and bring to bear on that evidence informed intellectual processes.

The ability of jurors to comprehend the evidence presented in a complex trial — that is, their capability to arrive at reasoned conclusions based upon that evidence — was expressly found to be an essential element of "due process" by the Third Circuit in *In re Japanese Electronic Products Antitrust Lit.*, 631 F.2d 1069 (3rd Cir. 1980) (hereafter "*Electronic Products*"):

> The primary value promoted by due process in fact-finding procedures is 'to minimize the risk of erroneous

> decisions.' [Citations.] A jury that cannot understand the evidence and the legal rules to be applied provides no reliable safeguard against erroneous decisions. Moreover, in the context of a completely adversary proceeding, like a civil trial, due process requires that 'the decisionmaker's conclusion . . . rest solely on the legal rules and evidence adduced at the hearing.' *Goldburg v. Kelly*, 397 U.S. 254, 271, 90 S.Ct. 1011, 1022, 25 L.Ed.2d 287 (1970). Unless the jury can understand the legal rules and evidence, we cannot realistically expect that the jury will rest its decision on them.
>
> *Id.* at 1084.

As Chief Judge Seitz concluded:

> Our liberties are more secure when judicial decisionmakers proceed rationally, consistently with the law, and on the basis of evidence produced at trial. If the jury is unable to function in this manner, it has the capacity of becoming itself a tool of arbitrary and erratic judicial power.
>
> *Electronic Products, supra*, at 1085.

The commentators, too, have identified a jury's ability to understand what has been perceived as an inherent requisite of "due process:"

> Due process is synonymous with fairness, and at a minimum would seem to require that the fact-finder be capable of rendering a reasoned verdict based upon an understanding of the evidence and the law.[5]

In a footnote supporting the foregoing proposition, the article's authors cite *Peters v. Kiff*, 407 U.S. 493 (1972):

> . . . [W]here the Supreme Court recently reaffirmed the well-established concept '*that the Due Process Clause protects*, a defendant from jurors who are ac-

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[5]Harris and Liberman, *Can the Jury Survive the Complex Antitrust Case?* 24 N.Y. Law Sch. L.Rev. 611, 620 (1979).

> tually incapable of rendering an impartial verdict, based on the evidence and the law.' *Id.* at 621, n.46 (emphasis added).

Similarly:

> Due process of law entails a process under which litigated matters will be decided by an arbiter within whose competence they lie. . . . To afford merely the opportunity to present evidence and argument in a forum unable to comprehend them is simply a mockery of justice.[6]

We certainly *do not* suggest, as recently has been advanced with some frequency,[7] that juries should have no role in deciding complex technical questions. However, we *do* assert — most vigorously — that the law is long-established that when an issue falls outside the ambit of common experience and knowledge, a jury of laymen is not competent to decide that issue in the total absence of testimony from a qualified expert or experts. Furthermore, it has long been established that questions of medical causation — such as that involved here — fall squarely within that rule.

This Court has properly observed that, "Maintenance of the jury as a fact-finding body is of such importance and occupies so firm a place in our history and jurisprudence that any seeming curtailment of the right to a jury trial should be scrutinized with the utmost care." *Dimick v. Schiedt*, 293 U.S. 474, 486 (1935). *See also, Beacon Theatres v. Westover*, 359 U.S. 500, 501 (1959).

We submit that the holding we attack "curtailed" Upjohn's constitutional right to trial by a "capable" jury. Allowing juries to decide the increasingly complex technical

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[6] J. Kirkham, *Complex Civil Ligitation — Have Good Intentions Gone Awry?* 70 F.R.D. 79, 208 (1976).

[7] *See* Commentaries, at p. 8 fn. 4.

issues raised in modern litigation without expert guidance would encourage suits predicated on facial plausibility rather than sound scientific principle, and deny plaintiffs and defendants alike their right to trial by "capable" jurors. The Fifth Circuit's adoption of a rule dispensing with the need for expert testimony in such circumstances is a constitutional infirmity which consequently ". . . should be scrutinized [by this Court] with the utmost care."

This Petition respectfully seeks such scrutiny.

B. THE RESULT BELOW RUNS CONTRARY TO LEGAL PRINCIPLES LONG-ESTABLISHED NATIONWIDE.

The propositions that 1) Juries are not competent to decide issues falling outside the ambit of common knowledge or experience without expert assistance; and 2) Complex questions of medical causation are just such issues, have been oft-repeated.

In a frequently cited opinion rendered before the turn of the century, for example, William Howard Taft — then a Circuit Judge and subsequently both President of the United States and Chief Justice of this Court — wrote:

> . . . [W]hen a case concerns the highly specialized area of treating an eye for cataract, or for the mysterious and dread disease of glaucoma, with respect to which a layman can have no knowledge at all, the court and jury must be dependent on expert evidence. There can be no other guide, and, where want of skill or attention is not thus shown by expert evidence applied to the facts, there is no evidence of it proper to be submitted to the jury.
>
> *Ewing v. Goode*, 78 Fed. 442, 444 (Cir. S.D. Ohio, W.D. 1897 [subsequently the 6th Circuit]).

The rule articulated in *Ewing v. Goode, supra*, respecting the indispensability of expert testing to proving medical causation has been adopted nationwide. In *Bearman v. Pru-*

dential Ins. Co. of America, 186 F.2d 662 (10th Cir. 1951), for example, the issue was whether a death was medically caused by an accident or by disease. As in the case at bar, a number of expert medical witnesses testified but, as in the case at bar, none of them testified that an accident suffered a number of weeks prior to the death in question was its medical cause. The Circuit found the absence of medical testimony regarding a causal connection between the accident and the death fatal to the plaintiff's case.

Addressing the insufficiency of the expert medical testimony, the Chief Judge wrote:

> Whether there was causal connection between the accident and resulting injury and the atherosclerosis, the rupture of the atheromatous abscess, the thrombosis, or the coronary occlusion presented a question for solution not within the competency of laymen, and a question with respect to which, only a medical expert with training, skill and experience could form a considered judgment and express an intelligent opinion. Indeed, it perhaps would require a medical expert trained and experienced in a specialized field.
>
> *Bearman v. Prudential Ins. Co. of America*, 186 F.2d 662, 665 (10th Cir. 1951).[8]

More recently, the Tenth Circuit reiterated the *Bearman* rule in the following terms:

> It is uniformly held that where injuries complained of are of such character as to require skilled and professional persons to determine the cause and extent thereof, they must be proved by the testimony of medical experts. . . .

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[8]Citing *Ewing v. Goode, supra*; the dissent in *United States Radiator Corp. v. Henderson*, 68 F.2d 87 (10th Cir. 1933) and cases there cited; and *Shepherd v. Midland Mut. Life Ins. Co.*, 152 Ohio St. 6, 87 N.E.2d 156, 160, 12 A.L.R. 2d 1250 (1949).

Franklin v. Shelton, 250 F.2d 92, 97 (10th Cir. 1957).

That *Bearman* is still alive and well as illustrated by the Tenth Circuit's 1981 opinion in *Curtis v. General Motors Corp.*, 649 F.2d 808 (10th Cir. 1981) where the court cited it for the proposition that ". . . the cause of death — the causal connection between the accident and the resulting injury — presented questions 'not within the competency of laymen' and the testimony of an expert was required." *Id.* at 813.

Learned Hand recognized the indispensability of expert testimony where "the origin and course" of a disease is concerned in *United States v. Clapp*, 63 F.2d 793 (2nd Cir. 1933). According to Judge Hand, whether the plaintiff suffered from a doudenal ulcer at the time his war risk insurance lapsed and whether the ulcer permanently disabled him,

> . . . was not for a jury to determine upon its own uninformed intuitions. It was a strictly medical question; without the help of those skilled in science, the conclusions of laymen upon such an issue were without adequate basis, and necessarily mere speculation. Only those familiar with the origin and course of the malady were competent to testify, and without testimony a verdict stood unsupported.
>
> *Id.* at 795.

Not long after Learned Hand's *Clapp* decision, the Fourth Circuit heard an appeal in another insurance case alleging accidental death. As in *Bearman*, those claiming under the policy in *Prudential Ins. Co. of America v. Bialkowski*, 85 F.2d 880 (4th Cir. 1936), argued that an accident had caused the insured's death. The carrier argued, to the contrary, that the insured had died from an unrelated ear disease. Conflicting expert testimony had been given regarding the cause of death. Wrote the Fourth Circuit:

> [W]e must look to the evidence of medical experts as to the cause of insured's death. [Citation omitted.] Such a question is purely medical.
>
> *Id.* at 882.

The Ninth Circuit considering a similar issue, wrote:

> It is well settled that only expert testimony will be allowed on technical questions of causation.
>
> *Frisone v. United States*, 270 F.2d 401, 403 (9th Cir. 1959).

Likewise the Eighth Circuit:

> [W]hen the causal relation issue is not one within the common knowledge of laymen, causation in fact cannot be determined without expert testimony.
>
> *Walstad v. University of Minnesota Hospitals*, 442 F.2d 634, 639 (8th Cir. 1971).

And more recently, the Second Circuit:

> Under New York law, except where 'the common experience and knowledge of a jury of laymen' can 'bridge this scientific gap' [citation omitted], a plaintiff has the burden of producing expert medical testimony showing proximate cause in medical malpractice actions.
>
> *Hegger v. Green*, 646 F.2d 22, 28 (2nd Cir. 1981).

The most recent federal appellate pronouncement of this principle we have found comes from the Fourth Circuit in a 1982 opinion which both cites and quotes *Ewing v. Goode*, *supra*, in several places — illustrating that venerable case's continuing vitality. As the Fourth Circuit views the rule:

> Just as negligence or violation of the standard of care [in a medical malpractice action] must ordinarily rest on expert opinion evidence, so proof of causation — that is that the defendant's negligence was 'more likely' or 'more probably' the cause of the plaintiff's injury — requires expert testimony.
>
> *Fitzgerald v. Manning*, 679 F.2d 341, 350 (4th Cir. 1982) (footnotes omitted).

State precedents regarding the indispensability of expert testimony to establish medical causation are equally consistent and even more numerous.[9]

As noted legal scholar, educator, and appellate advocate Erwin Griswold once observed — "The jury trial at best is the apotheosis of the amateur."[10] When the issues being tried transcend the competence of the amateur into the realm of the professional, the law is clear: Due process requires that the professionals — not the amateurs — guide the fact-finding process.

The record below made quite clear that pseudomembranes like Mr. Mauldin's may result from numerous causes, known and unknown. Identifying the cause of Mauldin's was a job for an expert, not a panel of laymen.

C. THE FIFTH CIRCUIT'S OFFHAND GENERALIZATION THAT FACTS MAY BE PROVEN BY BOTH DIRECT AND CIRCUMSTANTIAL EVIDENCE DOES NOT OBVIATE THE INDISPENSABILITY OF EXPERT TESTIMONY IN SUCH CASES.

1. Only Experts Are Competent to Draw Inferences of Medical Causation in Cases Such as Mauldin's.

In response to Upjohn's contention that "Mauldin failed to offer any direct medical evidence that either Lincocin or Cleocin probably caused his colitis," the Fifth Circuit cited

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[9]*See, e.g., Cullum v. Seifer*, 1 Cal.App.3d 20, 81 Cal.Rptr. 381 (1969); *Lysick v. Walcom*, 258 Cal.App.2d 136, 65 Cal.Rptr. 406 (1968); *Folk v. Kilk*, 53 Cal.App.3d 176, 126 Cal.Rptr. 172 (1975); *Shepherd v. Midland Mutual Life Ins.*, 152 Ohio 6, 87 N.E.2d 156 (1949); *Grismore v. Consolidated Products Co.*, 232 Iowa 328, 5 N.W.2d 646 (1942); *Spivey v. Atteberry*, 205 Okla. 483, 238 P.2d 814 (1951); *Uris v. State Compensation Dept.*, 247 Or. 420, 427 P.2d 753 (1967); *Stacey v. Williams*, 253 Ky. 353, 69 S.W.2d 697 (1934); *Longfellow v. Vernon*, 57 Ind. App. 611, 105 N.E. 178 (1914); *Anderson v. Nixon*, 104 Ut. 262, 129 P.2d 216 (1943); *Lorenz v. Lerche*, 157 Minn. 437, 196 N.W. 564 (1923); *Hirsh v. Safiarir*, 12 N.Y.Supp.2d 568, 257 A.D. 212 (1939); *Bowles v. Bourdon*, 148 Tx. 1, 219 S.W.2d 779 (1949); *Harrison v. Weller*, 423 S.W.2d 226 (Mo.App. 1967); *Senerjian v. Stetson*, 284 Mass. 510, 187 N.E. 829 (1933); *Wilson v. State Accident Insur. Fund*, 28 Or.App. 509, 560 P.2d 289 (1977).

[10]K. O'Connell, *Jury Trials In Civil Cases?*, 58 Ill. B.J. 796, 800 (1970).

the general proposition that, "The plaintiff's burden is to prove causation by a preponderance of the evidence, which may be met by direct or circumstantial evidence.' " *Mauldin v. Upjohn*, 697 F.2d 644, 646 (5th Cir. 1983), quoting *Porter v. American Optical Corp.*, 641 F.2d 1128, 1142 (5th Cir. 1981).

The Circuit's opinion cryptically follows this generalization with the observation that, "The record contains circumstantial evidence that either Lincocin or Cleocin caused Mauldin's disorder sufficient to require submission of that question to the jury." *Id.* at 646. Unfortunately, the Circuit chose not to identify the evidence from which it felt a lay jury could so infallibly infer that "either Lincocin or Cleocin caused Mauldin's disorder," even though neither Mauldin's treating physicians nor his (or anyone's) medical experts had so concluded or testified. Nor did it conclude that the causation issue in this case was so simple and straightforward as to fall within the ambit of common knowledge and experience. Indeed, given the record, it could not have so concluded.

We do not disagree with the general proposition that either direct or circumstantial evidence may be sufficient to support a finding of fact. But the Circuit's reference to this general proposition avoids, rather than meets, Upjohn's argument that experts alone are competent to find medical causation — whether they rely on direct *or* circumstantial evidence.

The Circuit's opinion miscarries in its failure to recognize that only experts were qualified to draw an inference of medical causation connecting Mauldin's use of Lincocin or Cleocin and his disease — whether based upon "circumstantial" evidence during trial or otherwise.[11] This they simply did not do.

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[11] *See*, F.R. Evid. § 801(b).

2. Laymen Could Not Rationally Infer Medical Causation From the Record in This Case.

The Circuit's failure to identify the circumstantial evidence which it found "sufficient" to justify the jury's finding of causation leaves us to speculate regarding just what it found so persuasive. An examination of the record, however, reveals *no* evidence which would justify allowing laymen to draw the necessary inference of causation.

The only evidence in the record which might bear on the causation question is as follows: First, a chronological or "temporal" relationship existed between Mauldin's use of the drugs and the subsequent onset of his symptoms. Second, one expert testified at trial that Cleocin-associated colitis is one type of pseudomembranous colitis associated with antibiotic therapy and, hence, that pseudomembranous colitis should be considered in a doctor's differential diagnosis of any patient who develops symptoms like Mr. Mauldin's while taking Cleocin or after recently having completed a course of Cleocin. Third, the warnings that accompany Lincocin and Cleocin state that cases of severe and persistent diarrhea have been reported in association with use of the drugs and that such diarrhea has at times resulted in acute colitis.

None of this evidence — taken collectively or separately — would support a conclusion by laymen that Mauldin's use of the drugs and the subsequent manifestation of his disease was anything other than rank concidence, as we now discuss.

a. The Temporal Relationship.

Mauldin's evidence regarding temporal relationships was essentially as follows:

1. Mr. Mauldin did not have a history of gastrointestinal problems prior to his thumb injury (al-

though he had suffered a kidney stone attack six weeks earlier);

2. Mr. Mauldin received treatment for his thumb injury with Lincocin and Cleocin; and,
3. Subsequent to Mr. Mauldin's use of the drugs, he developed a series of symptoms which one of his witnesses diagnosed at trial as pseudomembranous colitis.

Concluding that Mauldin's disease was caused by his use of the drugs simply because one followed the other is a classic illustration of the "post hoc ergo propter hoc" fallacy, which has been aptly described as "an obscure but melodious way of saying that there is no causal connection."[12]

The argument that a subsequent event is the result of a prior event based solely on this temporal relationship has consistently been rejected as fallacious by courts nationwide.

Most recently, the insufficiency of evidence of a temporal relationship to support a finding of causation has been reiterated in cases arising out of the federal government's Swine Flu Immunization Program. Pursuant to this program, over 40 million people received flu vaccine shots. Because many of those people *coincidentally* suffered medical problems of varying seriousness or at about the same time they took the shots, a flood of litigation ensued in which medical causation was the key issue. In such cases, the courts consistently have held that the existence of a simple temporal relationship is not sufficient to establish legal causation:

> The critical question presented in these cases is the causal relationship between the immunization and claimed illness. However, *mere temporal relationship*

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[12]*M & W Gear Company v. A. W. Dynamometer, Inc.*, 97 Ill.App.3d 904 (1981).

> *between the onset of a disease and the vaccination is insufficient to establish legal causation. . . .* All that has been shown here is a temporal relation; and that is insufficient to carry the burden of proof which rests upon plaintiff.
>
> *In re Swine Flu Immunization Products, etc.*, 533 F.Supp. 567, 572, 581 (D.C. Colo. 1982), (emphasis added).
>
> The relation of [plaintiff's injuries] with the administration of the swine flu vaccine, however, is a purely temporal connection. There is nothing in the record other than the mere time sequence to connect the vaccine with plaintiff's difficulties.
>
> *Lung v. United States*, 535 F.Supp. 100, 103 (E.D. N.Y. 1982).
>
> The Swine Flu program vaccinated over forty million people; coincidence of the shot and other unrelated events is inevitable.
>
> *Kubs v. United States*, 537 F.Supp. 560, 561 (E.D. Wis. 1982).

In *Gicas v. United States*, 508 F.Supp. 217, 219-220 (E.D. Wis. 1981), the court even rejected two *medical* opinions that the vaccine caused plaintiff's arthritis because each "was based on nothing more than a temporal relationship between the date of the swine flu innoculation and the onset of the plaintiff's injuries."

The consistent unwillingness of courts to accept temporal relationships as sufficient proof of causation is well justified. While an effect logically can never precede a cause, and thus a temporal relationship is an indispensable ingredient of causation, such a relationship, without more, does not *prove* causation.[13]

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[13]See, *United States v. Robison*, 644 F.2d 1270, 1273 (9th Cir. 1981); *United States v. Linton*, 655 F.2d 930, n.2 (9th Cir. 1981); *Foster v. United States*, 214 F.Supp. 181, 183-84 (S.D. Miss. 1963); *Genesee Merchants Bank and Trust Co. v. Payne*, 161 N.W.2d 17, 24 (S. Ct. Mich. 1968); *Tremaine v. H. K. Mulford Co.*, 176 A. 212, 215 (S.Ct. Pa. 1935).

If temporal relationships are insufficient to support expert opinions regarding medical causation, *a fortiori*, they are insufficient to justify such inferences by laymen.

b. Simply Because the Drugs Occasionally Can Cause Such Disease Is Insufficient to Establish That They Did in This Case.

There was also evidence from a leading national expert on pseudomembranous colitis, Dr. Francis Tedesco, that:

> It appears that the entity of Clindamycin-associated colitis is simply *another example* of pseudomembranous colitis associated with antibiotic therapy. . . . *Pseudomembranous colitis should now be considered in a differential diagnosis* of any patient who develops elevated temperature, ileus, or diarrhea while taking Clindamycin or after recently having completed a course of Clindamycin.
>
> (R.T. Vol. V, p. 44, emphasis added.)

Dr. Tedesco's testimony does no more than support the proposition — which we do not dispute — that Cleocin, like all other antibiotics, may cause pseudomembranous colitis on occasion. Just as the *possibility* that there might be a causal connection between the alleged cause and suspected effect was not sufficient to prove causation in *Bearman, supra*, the *possibility* of causal connection raised by Dr. Tedesco's testimony falls well short of establishing the requisite probability in this case.

Significantly, neither Dr. Tedesco nor anyone else opined that Cleocin or Lincocin even *might* have caused Mr. Mauldin's colitis. In any event, a *possibility* is not sufficient to support a finding of causation.

c. The Warnings.

The last item of "circumstantial" evidence to which the Circuit may have been alluding was a reference in the warnings accompanying the drugs to the effect that cases of

severe and persistent diarrhea have been reported in association with the use of the drugs and, at times, have resulted in acute colitis. See, *Mauldin, supra* at 697 F.2d at 646, n.2.

Ironically, a major issue at trial was Mauldin's claim that those warnings about the possibility of colitis were *inadequate to inform prescribing doctors* that the drug might cause Mauldin's disease. Indeed, throughout the trial, Mauldin presented expert testimony that the warnings did not adequately inform doctors that the drugs may cause pseudomembranous colitis (*see*, R.T. Vol. II, p. 62).

In order to hold Upjohn liable for its failure adequately to warn prescribing physicians of the possibility that the drugs might cause pseudomembranous colitis, the jury itself must have found the warnings *inadequate* to notify even practicing physicians of the risk. If, as the jury necessarily found, the Lincocin and Cleocin warnings were *inadequate* to inform *experts* (prescribing physicians) of the risk of a possible causal relationship between the drugs and pseudomembranous colitis, we submit it would be impossible for a lay jury to infer a causal connection in Mauldin's case based upon such warnings.

d. Without Expert Testimony on Causation, the Jury's Conclusion That the Drugs Caused Mauldin's Illness Was Mere Speculation.

It is hornbook law that, for evidence to be sufficient to warrant a finding of fact by a jury, ". . . the circumstances must lead to the conclusion with *reasonable* certainty, and must have *sufficient probative force* to constitute the basis for a legal inference and not for mere speculation." 32A C.J.S. § 1039 (emphasis added). As the foregoing discussion makes clear, however, there was *no* evidence from which a jury — as opposed to an expert — could reasonably infer that the drugs in question caused Mauldin's disease.

The Circuit's causal observation that causation may be proved by either direct or circumstantial evidence totally misses the point. Both direct evidence (finding a bottle cap in a child's stomach and concluding that the sharp-edged cap is the cause of bleeding lacerations in the child's throat and stomach) and indirect evidence (using blood tests, electro-cardiograms, work and medical histories, blood pressure tests, and the like, to conclude that work-related stress has caused a heart attack) are certainly indispensable to medical experts in diagnosing, identifying the cause or causes of, and treating diseases. Except in the most unusual circumstances, however, laymen are not qualified to make such diagnoses, to identify causal relationships, or to decide upon proper courses of treatment. These things the experts must do. This is especially so in cases involving rare and esoteric diseases such as pseudomembranous colitis.

We submit that because the jury was not legally competent to infer that Mauldin's use of Lincocin or Cleocin medically caused his disease, their conclusion that a causal connection existed must have been based upon impermissible speculation, conjecture, or surmise. As Learned Hand put it, "[w]ithout the help of those skilled in science, the conclusions of laymen upon such an issue were without adequate basis, and necessarily mere speculation." *Clapp, supra*, 63 F.2d at 795.

D. THE FIFTH CIRCUIT'S *MAULDIN* OPINION RADICALLY DEPARTS FROM LONG-ESTABLISHED PRECEDENT IN THE CIRCUIT AS INTERPRETED BY THE SUPREME COURT.

Bearman v. Prudential Ins. Co. of America, supra, 186 F.2d 662 (10th Cir. 1951), already discussed at some length, involved extensive medical testimony. As in the instant case, however, *none* of the experts in *Bearman* testified that they believed that an accident suffered by the decedent more

probably than not caused the disease which undisputedly killed him, even though the onset of his disease followed closely on the heels of the accident.[14] Hence, the plaintiff lost.

More than a decade ago *Bearman* was cited with approval by the Fifth Circuit in *Webster v. Offshore Food Service, Inc.*, 434 F.2d 1191 (5th Cir. 1970), which expressly held that a trier of fact may not substitute its own "practical judgment" for that of the experts where ". . . the testimony bears on technical questions of medical causation beyond the competence of lay determination." *Id.* at 1193.

Furthermore, the law of the Circuit has long been that such expert testimony must be to the effect that the causal connection is *probable*, as expressly stated in *Inter-Caribbean Shipping Corporation v. Sentilles*, 256 F.2d 156 (5th Cir. 1958), where the Circuit cited *Bearman* for the following proposition:

> It appears to be well settled that medical testimony as to the possibility of a causal relation between a given accident or injury and the subsequent death or impaired physical or mental condition of the person injured is not sufficient, standing alone, to establish such relation. By testimony as to possibility is meant testimony in which the witness asserts that the accident or injury 'might have,' 'may have,' or 'could have' caused, or 'possibly did' cause the subsequent physical condition or death or that a given physical condition (or death) 'might have,' may have,' or 'could have' resulted or 'possibly did' result from a previous accident or injury — testimony, that is, which is confined to words indicating the possibility or chance of the existence of the causal relation in question and does not include

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[14]Unlike the instant case, there was expert testimony in *Bearman* that the injury *might have* caused the death. No such testimony was given in this case.

words indicating the probability or likelihood of its existence. * * * 135 A.L.R. 516.

Inter-Caribbean, supra, at 158.

While the Supreme Court reversed the Circuit's holding in *Sentilles*, it did so not because it found the Circuit's statement of the law deficient, but because, contrary to the Circuit, it found sufficient expert medical testimony in the record to establish probable medical causation. *Sentilles v. Inter-Caribbean Shipping Corp.*, 361 U.S. 107 (1959).

The dispositive issue in *Sentilles* was whether a shipboard accident "activated or aggravated" the plaintiff's preexisting but dormant tubercular condition. Much medical testimony was given on the topic. Despite expert testimony that "the fall probably aggravated" the tuberculosis, the Fifth Circuit found that the most the testimony established was that "the incident was a possible cause of the aggravation." *Inter-Caribbean, supra*, at 158.[15]

The Supreme Court reversed, holding that the expert testimony was indeed sufficient to establish a probable causal connection between the plaintiff's accident and his disease: One specialist testified that, based upon his examination of x-rays taken before the injury, he "felt" that the plaintiff was tubercular before the accident and that " 'acute dissemination of the tuberculosis' might be a consequence of the accident." (361 U.S. 109). A second specialist opined that the accident and the plaintiff's diabetes were "the most likely causes of the aggravation of the tuberculosis", although he was not able to state "which of the two it is more likely was responsible in this instance." (*Id.*) A third expert said he "was of the opinion that the accident 'probably aggravated [plaintiff's] condition,' though he would not say

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[15]In the instant case, no expert even speculated about a possible cause of Mauldin's disease.

definitely. . . ." (*Id.*)

In finding the above testimony sufficient, the Supreme Court held, in essence, that, "the matter does not turn on the use of a particular form of words by the physicians in giving their testimony. . . ." (*Id.*) Clearly, so long as the substance of the expert testimony is that causation *probably* exists, that will be sufficient, even though the "magic words" of probability have not been used.

This Court's *Sentilles* opinion thus simply cannot be read as abrogating the need for expert testimony to prove medical causation (although it concededly has been miscited in support of that proposition on occasion[16]). At most the opinion stands for the proposition that an expert testifying about medical causation need not use the magic words of "probability," so long as his testimony — taken as a whole — is to the effect that the causal relationship is "probable."

Nor does the opinion in *Porter v. American Optical Corp.*, 641 F.2d 1128 (5th Cir. 1981), cited by the Fifth Circuit in support of dispensing with the need for expert medical testimony in *Mauldin*, stand for the proposition that expert testimony is not needed where medical causation is the issue. *Porter* expressly alludes to extensive expert testimony to the effect that the injured party had a "strong case of asbestosis" and that "asbestosis was a significant and major condition leading to [Porter's] death." *Id.* at 1142.

The Circuit accepted as proven that breathing asbestos causes a concentration of asbestos particles in the lung; that a sufficiently high concentration and buildup of asbestos in the lung will cause death; and that this disease process —

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[16]*Picou v. American Offshore Fleet*, 576 F.2d 585, 588 (5th Cir. 1978); *Fitzgerald v. A.L. Burbank Co.*, 451 F.2d 670, 681 (2nd Cir. 1971); *Petition of U.S. Steel Corporation*, 436 F.2d 1256, 1265 (6th Cir. 1970); *Denney v. Siegel*, 407 F.2d 433, 441-442 (3rd Cir. 1969).

called asbestosis — can also be a precipitating cause of other illnesses such as emphysema, bronchitis, and pneumonia. *Id.* at 1133. Whether inhalation of asbestos medically caused the plaintiff's disease *was thus not in issue.*

To the contrary, the question in *Porter* was whether a respirator used by the decedent, Porter, and manufactured by defendant American Optical was defective in that it unreasonably exposed Porter to the acknowledged medical cause of his deadly disease — breathing asbestos — because large quantities of asbestos particles could pass through its filter.

Defendant American Optical challenged the sufficiency of the testimony of an expert toxicologist, Dr. William George, who testified regarding the results of an experiment he had conducted to determine the percentage of asbestos fibers which passed through the type of respirator which plaintiff asserted was defective. Dr. George was *not* qualified by the Court as an expert in respirator or filter design. *Id.* at 1134. He was, however, a qualified toxicologist — a specialist in the effects, detection, and treatment of poisons. In Dr. George's opinion, based upon tests he had personally conducted, an estimated 18% to 20% of the asbestos particles in the ambient air surrounding a user of the respirator passed through its filter. It would not require an expert to conclude that most, if not all, of the asbestos particles which passed through the filter would have been breathed by a user of the device. Given the fact that the ambient air where Porter worked was loaded with asbestos particles, and the conceded fact that breathing asbestos is the medical cause of asbestosis, the link between the defect (the failure of the respirator to filter out the asbestos) and Porter's disease (asbestosis) was complete *based upon expert testimony.*

Porter thus supports, rather than detracts from, the proposition that expert testimony is necessary to support technical conclusions and that where such issues are involved, an expert, and not the jury, must draw the necessary technical inferences from either direct or circumstantial evidence.

Where experts have testified but equivocated, courts have still been reluctant to say causation was established. In *Curtis v. General Motors*, 649 F.2d 808 (10th Cir. 1981), for example, a medical expert said he could not ascertain "with any degree of certainty" that a disc injury sustained by the plaintiff was caused by the manufacturer-defendant's alleged inadequate rollover protection. In *Curtis*, the Tenth Circuit (citing *Bearman*) reversed the lower court's judgment in favor of the plaintiff saying:

> The jury could not express a lay opinion as to the cause of the injury when the medical witness was unable to express an expert opinion.
>
> *Id.* at 813.

The court then went on to say:

> Expert testimony is required in order for the jury to avoid pure speculation, or a conclusion arising from the plaintiff's position after the accident but with no causal connection to the injury established by anyone's testimony.
>
> *Id.* at 813.

We submit that inability, unwillingness, or a simple unexplained failure of an expert to express such an opinion constitutes just such a fatal absence of evidence.

Conclusion.

In summary, the indispensability of expert testimony in proving medical causation in cases like this one has long been recognized in the Fifth Circuit, as elsewhere. The practical effect of the Circuit's offhand allusion to the

sufficiency of circumstantial evidence is to totally abrogate that rule, and would foster litigation of highly technical issues based on the popular appeal of an argument rather than its scientific soundness.

This Court should not permit jury trials in the Fifth Circuit to degenerate into no more than "the opportunity to present evidence and argument in a forum unable to comprehend them," or to predicate substantial liability on a jury's "uninformed institutions." Indeed, such a result would be repugnant to established constitutional concepts of due process.

We respectfully urge that this Petition for Certiorari be granted as a step toward avoiding that unfortunate result.

Respectfully submitted,

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APPENDIX A.

Opinion.

O.L. Mauldin, Plaintiff-Appellee v. The Upjohn Company, Defendant-Appellant. No. 81-3209.

United States Court of Appeals, Fifth Circuit.

Feb. 7, 1983.

Plaintiff, a consumer of antibiotic drugs who suffered serious adverse reactions to them, brought products liability action against drug manufacturer. The United States District Court for the Eastern District of Louisiana, Veronica D. Wicker, J., entered judgment in favor of plaintiff, and manufacturer appealed. The Court of Appeals, Politz, Circuit Judge, held that: (1) evidence that either of the two antibiotic drugs probably caused plaintiff's condition was sufficient for jury; (2) evidence of inadequacy of manufacturer's warnings of possible adverse effects from use of drugs was sufficient for jury; (3) trial court did not err in admitting into evidence certain "adverse reactions" reports; (4) trial court did not err in admitting into evidence photographs made by pathologist displaying slides of colon tissue assertedly taken from plaintiff; (5) jury instructions were proper; and (6) plaintiff's statements of religious belief while testifying to hardships imposed upon him in efforts to attend church because of present condition were not unduly prejudicial.

Affirmed.

Henry B. Alsobrook, Jr., Robert D. Bjork, Jr., New Orleans, La., for defendant-appellant.

Francipane, Regan & St. Pee, Philippi P. St. Pee, Metairie, La., for plaintiff-appellee.

Appeal from the United States District Court for the Eastern District of Louisiana.

Before GARZA, POLITZ and WILLIAMS, Circuit Judges.

POLITZ, Circuit Judge:

In this product liability diversity case, the Upjohn Company, manufacturer of the antibiotics Lincocin and Cleocin[1] appeals an adverse verdict in favor of plaintiff O.L. Mauldin, contending that: (1) Mauldin failed to establish a causal link between the drugs and his condition, (2) Mauldin failed to establish the inadequacy of the manufacturer's warnings, (3) the trial judge ruled erroneously on evidentiary matters, and (4) the judge erred in her jury charge. Finding no reversible error, we affirm.

Facts

Mauldin severely injured his hand in March 1974 while working on a lake barge. He was treated by Dr. Herman E. Walker, Jr., who prescribed Lincocin as a guard against infection. When Dr. Walker released Mauldin from the hospital, he prescribed Cleocin as a continuing prophylaxis against infection. Mauldin was scheduled for a follow-up examination in three weeks.

Shortly after leaving the hospital, Mauldin began to suffer from a tenacious bout of diarrhea. He was treated by several physicians, one of whom prescribed the drug Lomotil, but his condition worsened and he was readmitted to the hospital. Mauldin's physical condition continued to deteriorate, and he was ultimately subjected to multiple and extensive surgical procedures made necessary by ulcerative colitis. The period of hospitalization exceeded two months.

This tort action began in state court, was removed to federal court and initially ended in a mistrial. On retrial the jury returned a verdict for $570,000, grounding liability on a finding that Upjohn had failed to warn adequately of the

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[1]Lincocin and Cleocin are Upjohn's trade names for lincomycin and clindamycin HCl, respectively.

risk of pseudomembranous colitis posed by the two drugs. The instant appeal follows the denial of the motion for judgment n.o.v. or new trial.

Causation

Upjohn challenges causation on two grounds. It first contends that Mauldin failed to offer any direct medical evidence that either Lincocin or Cleocin probably caused his colitis. In response we note that failure to produce direct medical evidence is not fatal, for as we observed in *Porter v. American Optical Corp.*, 641 F.2d 1128, 1142 (5th Cir.1981), a products liability case involving Louisiana law, "The plaintiff's burden is to prove causation by a preponderance of the evidence, which may be met by direct or circumstantial evidence." In a case of circumstantial evidence, Upjohn maintains that Mauldin must exclude all other reasonable hypotheses of causation if he is to prevail based on such evidence. We disagree. Mauldin does not bear that onerous burden; his "evidence need not negate all other possible causes." *Id. (citing Weber v. Fidelity & Casualty Ins. Co. of New York*, 259 La. 599, 250 So.2d 754 (1971), and *Jordan v. Travelers Ins. Co.*, 257 La. 995, 245 So.2d 151 (1971)). The record contains circumstantial evidence that either Lincocin or Cleocin caused Mauldin's disorder sufficient to require submission of that question to the jury.

Upjohn's second challenge to causation relates to the warnings. Essentially, Mauldin complained that the warnings[2] on the package inserts did not adequately inform

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[2]The following information was recited under the heading "Adverse Reactions":

> Gastrointestinal: Abdominal pain, nausea, vomiting and diarrhea or loose stools may occur. Cases of severe diarrhea associated with blood and mucus in the stools have been reported.

Additionally, the following warning was stated in the package insert

(footnote continued on following page)

his physician of possible adverse reactions to the two antibiotics. Because of this failure, Mauldin contended that Upjohn is liable for the damages caused by his adverse reaction to the drugs.

In its defense to these contentions, Upjohn refers to the testimony of Dr. Walker, the prescribing physician, which indicates that he would have prescribed the medications, despite stronger warnings, because of the danger of infection and the reputation of the drugs. Upjohn argues that Dr. Walker's testimony establishes that any failure on its part to warn adequately of potential side effects of the medications was not causally related to the later tragic events.[3] Upjohn maintains that Dr. Walker's testimony severs the causal chain.

This argument is appealing but not compelling for Dr. Walker also testified that the regimen he would have followed would have differed if he had been made aware of the severity of the side effects and of the suggested treatment

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and was published in the *Physician's Desk Reference (PDR)*:

> WARNINGS
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> The following reactions have been reported with the use of clindamycin [Cleocin].
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> CASES OF SEVERE AND PERSISTENT DIARRHEA HAVE BEEN REPORTED AND HAVE AT TIMES NECESSITATED DISCONTINUANCE OF THE DRUG. THIS DIARRHEA HAS BEEN OCCASIONALLY ASSOCIATED WITH BLOOD AND MUCUS IN THE STOOLS AND HAS AT TIMES RESULTED IN ACUTE COLITIS.

[3]We note the following colloquy between counsel for Upjohn and Dr. Walker.

> Q. And with regard to—Doctor, I am going to ask you this: You said that you didn't know about pseudomembranous colitis at the time, but even if you had known about it, knowing that the Cleocin was the best drug on the market to give Mr. Mauldin, you would have given it to him, anyway, wouldn't you?
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> A. I probably would have at the time because there was really no adequate substitute to use.

of the induced diarrhea.[4]

The manufacturer of a prescription drug is not obliged to warn each consumer of the dangers inherent in the use of its product if the prescribing physician receives adequate warnings of the potential adverse effects. *See Givens v. Lederle*, 556 F.2d 1341 (5th Cir.1977); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974). Upjohn

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[4]Dr. Walker testified on cross-examination:

Q. Dr. Walker, you said you might have given the drug Cleocin anyway. But I am asking you if you would have given the drug Cleocin anyway, you would have given the drug under the belief that you knew what its side effects were, is that correct?

A. Yes sir.

Q. And if you knew that a side effect of a particular drug which you may give to your patient could cause the onset of a certain sign of symptoms of that disease, would you not yourself be more alert for the onset of those signs, and at the same time advise your patient to be more alert for the onset of those signs and symptoms of this particular adverse reaction?

A. Yes, sir, usually so. If you could expect something to happen, but on the other hand, I may not have told him all of the side effects.

You know, sometimes I do, sometimes I don't.

Q. But if you are concerned about a particular side effect or if you know about a particular side effect and your patient walks back into your office a couple days later or a couple weeks later and says, Doctor, I am in this conditoin, and he describes his condition to you, and then you know that the condition he has been describing is the onset of a particular side effect. You would then know how to treat your patient to avoid a more debilitating, progressively debilitating type of condition, is that correct?

A. Yes, Sir.

Q. Now—

A. Usually you do, if there is a treatment for it.

Q. That's part of the thing you want to do for your patient, it's not only to fix his thumb, but it is also to make certain in fixing his thumb he returns to good and full health rather than being started on a chain of downward health?

A. Of course. You want to treat the whole patient, not just the thumb.

Q. You mentioned one of the things that you considered in the package insert was the antidote, is that correct, the treatment or—

A. Well, I was saying that sometimes they will list an antidote for a drug. There is no antidote listed for Cleocin.

contends that its warning, *see* note 2, was sufficient to alert Dr. Walker of the potentially dangerous side effects of Cleocin and Lincocin. Although the contention has force, we are not convinced that it must be accepted as a matter of law. Rather, in the factual panorama presented by this case, the contention poses a jury question.

In *Timm v. Upjohn Co.*, 624 F.2d 536, 539 (5th Cir.1980), *cert. denied*, 449 U.S. 1112, 101 S.Ct. 921, 66 L.Ed.2d 840 (1981), a case also involving Cleocin, we concluded that in deciding whether the identical warning was sufficient, "The jury was entitled to weigh the conflicting statements made by [the prescribing doctor] and the other physicians along with all the other evidence presented in the case." The instant case poses the same question. The jury heard and was called upon to evaluate Dr. Walker's testimony as to what he understood the warnings to be and how he might have acted differently if he had been warned or advised differently. In addition to the testimony that he probably would have prescribed the drugs regardless of the more detailed warning, there is further testimony about potential monitoring and cautionary advice to Mauldin and the impact of the failure to list any remedies or antidotes for adverse reactions. The evidence presented dictates neither an affirmative nor a negative answer to the inquiry whether Dr. Walker would have acted differently if the warnings had been different. Instead, the evidence presents the classic question for the trier of fact—in this instance the jury.

Inadequate Warnings

To establish his challenge to the inadequacy of the warnings for Lincocin and Cleocin in the package inserts and in *Physician's Desk Reference*, Mauldin offered the testimony of Dr. Walker as well as that of Dr. Gordon McHardy, an internist specializing in gastroenterology. Dr. McHardy was

of the opinion that the Upjohn warning did not notify the practicing physician of the danger of pseudomembranous colitis as a possible adverse reaction to the use of Cleocin or Lincocin nor advise of any method of treatment for complications arising from the use of the drugs. Although Upjohn considered Lomotil to be contraindicated in the treatment of Cleocin diarrhea, its warning did not so advise. Dr. McHardy spoke of the imperative that doctors be "adequately advised as to the side effects of drugs" which they prescribe. Dr. Walker concurred.

Upjohn counters with the testimony of Dr. Francis Tedesco, an expert in the drafting of warnings such as those here involved. At trial, Dr. Tedesco attested to the adequacy of the warnings. Upjohn insists that only an expert in the preparation or construction of medical product warning statements can testify properly as to the issue of adequacy. We cannot accept this argument, for it belies the essential purpose of the warning. Package inserts and *PDR* references are not written for medical experts schooled and skilled in the writing of warnings. They are written to inform fully and adequately the medical practitioner who is called upon—occasionally importuned—to prescribe the medication. The understanding and perception of the Dr. Walkers and Dr McHardys is entirely relevant, for the sufficiency of the warning is dependent upon their reasonably anticipated comprehension. The record contains sufficient evidence to support the jury's finding that the warnings were inadequate.

Evidentiary Rulings

Upjohn questions the admission into evidence of certain "adverse reactions" reports,[5] offered to establish Upjohn's awareness of the problems associated with use of the subject

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[5]The "adverse reaction" reports are completed by a physician or hospital personnel and forwarded to the drug manufacturer, informing the manufacturer that a patient has suffered from a reaction of side effects which is not detailed on the package insert.

drugs. Since many of the reports detailed complications other than pseudomembranous colitis, thereby going beyond the issue in this case, Upjohn argues that the probative value of the reports was outweighed by their prejudicial nature, adversely affecting the jury.[6]

Our review of the record leads us to conclude that while Mauldin's counsel should not have been permitted to dwell on the reports, the trial judge's limiting instruction[7] prevented the type of possible jury confusion criticized by the Supreme Court in *Bruton v. United States*, 391 U.S. 123, 88 S.Ct. 1620, 20 L.Ed.2d 476 (1968).

Upjohn also attacks, on grounds of authentication, the admission of photographs made by pathologist Francis M. Patton displaying slides of colon tissue. Dr. Patton prepared the slides from paraffin blocks furnished by another pathologist. On cross-examination, Dr. Patton candidly conceded that he could not attest "with absolute certainty" that the paraffin blocks contained tissue taken from Mauldin. Dr. Patton did testify, however, that the numbers on the pathology reports identified as Mauldin's were identical to the numbers on the paraffin blocks identified as Mauldin's, and that he observed nothing to indicate a mix-up. Dr. Patton expressed no doubt as to the match itself. The Federal Rules of Evidence do not require absolute certainty in authentication, but rather "evidence sufficient to support a finding that the matter in question is what its proponent claims." Fed.R.Evid. 901(a). This measure is met; the photographs were properly admitted.

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[6]Upjohn also objected to the admission of the reports on hearsay grounds. Hearsay is not implicated, however, since the reports were not offered to prove the truth of their contents. *See* Fed.R.Evid. 801(c).

[7]The trial judge instructed the jury that these reports could be considered solely on the issue of notice; they were not to be considered for the truth of their contents.

Jury Instructions

Upjohn questions the trial judge's statement that "the Upjohn Company failed to timely advise physicians as to the proper method of treating adverse reactions to these drugs" and her reference to "ulcerative-like pseudomembranous colitis." We accept, *arguendo*, the substantive validity of the challenges to this statement and reference. Having done so, we examine the entire jury charge. "In reviewing the trial judge's instructions to the jury, we consider the charge as a whole to determine whether the jury was misled and whether it understood the issues presented." *Timm v. Upjohn Co.*, 624 F.2d at 539 (*citing Coughlin v. Capitol Cement Co.*, 571 F.2d 290 (5th Cir. 1978), and *Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076 (5th Cir.1973)). Assessed in the light of this rubric, the judge's instructions pass muster, since the charge as a whole makes clear that it was the jury's province to determine the facts, including the adequacy of Upjohn's notice procedures.

Upjohn's final assignment of error requires little discussion. Upjohn contends that Mauldin's testimony, by touching on his practice of attending church and his belief in "almighty God," violated Fed.R.Evid. 610 and was unduly prejudicial. This argument is without merit. The record reveals that Mauldin was not attempting to bolster his credibility through his statements of religious belief but simply was testifying to the hardships imposed upon him, in his efforts to attend church, because of his present condition.

AFFIRMED.